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THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF APPEALS

Appellant:	David R. MacLean	)	
Serial No:	09/550,049	)	
Filed:	April 14, 2000	)	
For:	SAFETY DEVICE FOR USE WITH A VIAL	)	Appeal No.

REQUEST FOR REINSTATEMENT OF THE APPEAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellant hereby requests the reinstatement of the appeal for the instant application in response to the Office Action dated May 24, 2006. This Request is accompanied by the attached Appeal Brief.

As the fee for the previous Appeal Brief has been paid, the Commissioner is respectfully requested withdraw $220.00 from Deposit Account No. 50-0501, which is the difference between the fee for filing the Appeal Brief presently as compared to when the last Appeal Brief.

The Commissioner is further authorized to charge any fee deficiency, or credit any overpayment, to Deposit Account No. 50-0501.

Respectfully submitted,

Adjusment date: 09/19/06 MBLANCO
08/30/06 MBERHE 00000001 500501 09550,049
01 FC: 1401 500 CR.

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Date: Sept 13, 2006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF APPEALS

Appellant:	David MacLean	)	
		)	
Serial No:	09/550,049	)	Art Unit: 3767
		)	
Filed:	April 14, 2000	)	Examiner: Gray, Phillip A.
		)	
For:	SAFETY DEVICE FOR USE WITH A VIAL	)	Attorney Docket: 0100/0091
		)	
		)	

APPEAL BRIEF

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REAL PARTY IN INTEREST

The real party in interest for this appeal is Smiths Medical ASD, Inc., which is the successor entity in interest of SIMS Portex Inc., to which the inventor assigned his interest per an Assignment recorded on April 14, 2000 with the Assignment Branch of the U.S. Patent and Trademark Office.

RELATED APPEALS AND INTERFERENCES

Applications concurrently being appealed by the real party in interest are: application No. 09/920,860 appeal brief filed September 22, 2003 entitled "Needle Safety Device With Tortuous Path", application No. 09/962,240 appeal brief filed October 12, 2004 entitled "Needle Protection Device With Dampener", and application No. 10/925,962 appeal brief filed May 30, 2006 entitled "Needle Protection Device With Gauge Specific Color Coding And Method For Manufacturing Thereof". It is the belief of appellant that none of the noted appeals would directly affect or be directly affected by or have any bearing on the Board's decision in the pending appeal.

STATUS OF CLAIMS

Claims 1-27 are in the application. Claims 7-21 were withdrawn from further consideration per an Office Action dated November 5, 2002.

Claims 22-27 were appealed per an Appeal Brief filed on April 20, 2004. A 1st request for re-instatement of the appeal was filed on February 11, 2005 in response to the reopening of the prosecution per an Office Action dated December 13, 2005. A 2nd request for re-instatement of the appeal was field on March 22, 2005 in response to the re-opening of the prosecution per an Office Action dated March 7, 2005.

Claims 1-6 and claims 22-27 have been rejected by the examiner per the latest Office Action dated May 24, 2006.

The instant appeal brief is being filed to reinstate the appeal.

Claims 1-6 and 22-27, each having been rejected by the examiner, are hereby on appeal. The being appealed claims are listed in the attached Claims Appendix A.

For the convenience of the Board, withdrawn claims 7-22 are listed in the attached Claims Appendix B.

STATUS OF AMENDMENTS

There was no amendment filed subsequent to the Office Action of May 24, 2006.

SUMMARY OF THE CLAIMED SUBJECT MATTER

Independent claim 1 recites a safety device usable with a vial (8) [Figs. 7 and 8] that has mounted to one of its ends a hub (28) from which a needle (26) extends. The hub has a shoulder (33) and a base. The safety device of claim 1 comprises a collar (4) that is slidably matable about the vial (8), with the collar having a distal end [Figs. 1-4; page 5, line 15-19]. There is also included in the safety device of claim 1 a neck member (12) that extends from the distal end of the collar [Figs. 1-4; page 5, lines 18-19]. A housing (14) is pivotally connected to the end of the neck member (12) away from the collar (4) [Figs. 1-4; page 5, lines 19-22]. There is also included in the safety device of claim 1 a latch member (20) that extends from the neck member (12) in a direction towards the center of the collar (4). The latch member coacts with the shoulder (33) of the hub (28) [of the vial], and the distal end of the collar (4) coacts with the base of the hub (28) to prevent the collar (4) from being removed from the vial (8) once the collar (4) has been mated about the vial (8) and the distal end (4u) of the collar (4) is positioned adjacent to the hub (28) [Figs. 1-4; page 5, line 23 to page 26, line 5; page 6, line 19 to page 7, line 16 (see also amended paragraphs in the Amendment dated August 5, 2003)].

The instant invention, as set forth in independent claim 22, relates to a safety device (2) that comprises a collar (4), a neck (12) extending from the collar, a housing (14) pivotally connected to the end of the neck away from the collar and a latch member (20) that extends from the neck in a direction towards the center of the collar. When the collar is placed about a vial (8) and moved towards a hub (28) of the vial until it is adjacent to one end of the hub, the latch member latches onto the other end of the hub [Figs. 1-8; page 5, line 15 to page 8, line 14].

Independent claim 25 recites a safety device that comprises a collar (4), a flexible neck (12) extending from the collar, a housing (14) pivotally connected to the end of the neck away from the collar, and a latch member (20) that extends from the neck in a direction towards the center of the collar. For the invention set forth in the claim 25 embodiment, the latch member would continuously bias against the body of a vial (8) when the collar is placed about the vial and moved towards one end of the hub (28) of the vial. The latch member would latch onto another end of the hub when the collar is moved adjacent to the one end of the hub [Figs. 1-8; page 5, line 15 to page 8, line 14].

The instant invention is therefore directed to a safety device that has a collar that slidingly fits onto the body of a vial and is moved toward the hub of the vial, so that when the collar is adjacent to one end of the hub, the latch member at the neck that extends from the collar would latch onto the other end of the hub of the vial to thereby retain the collar to the vial. The housing that is attached to the other end of the neck away from the collar could then be pivoted to cover the needle that extends from the hub of the vial, per defined in claims 24 and 27.

The dependent claims that are discussed herein and which should be adjudged separately from the independent claims include claims 2-4, 6, 23 and 26.

Claim 2, which depends from claim 1, recites that the latch member (20 is integrated to the neck member (12), with the neck member being flexible with respect to the collar (4) so that the latch member is guided along the side of the hub (28) as the collar is moved towards the hub. The latch member (20) latches onto the shoulder (33) of the hub when the collar is moved adjacent to the hub [page 6, lines 19 to page 7, line 16].

Claim 4 also depends from claim 1. Claim 4 defines the neck member (12) being flexible with respect to the collar so that once the collar is moved to a given position relative to the hub, the neck member flexes to a position to enable the latch member (20) to latch onto the shoulder of the hub. Claim 4 further recites that the needle and the housing (14) interact to prevent the neck member (12) from flexing away from the hub and the latch member (20) from being disengaged from the shoulder of the hub, once the locking means (32) is fixed relative to the needle (26) when the housing has been pivoted to a position in substantial alignment with the longitudinal axis of the vial (8) [page 8, lines 1-14].

Claims 2 and 4 thereby each require that the neck member is flexible with respect to the collar as the collar is moved relative to the vial.

Claim 3, which depends from claim 1, defines in detail the latch member (20) by reciting that the latch member is integrated to a location along the neck member (12) so as to effect a space between a latch member and the collar (4) along the neck member whereinto the hub (28) matingly fits after the collar (4) is moved adjacent to the hub and

the latch member is moved into position to latch onto the shoulder (33) of the hub [Fig. 5; page 5, line 24 to page 6, line 5; page 7, lines 17-23].

Claim 6, which depends from claim 1, defines the neck member (12) to be a flexible upright extending from the collar. The latch member (20) comprises a lip (22) extending at its tip, with the lip latching onto a shoulder (33) of the hub (28) [of the vial] when the collar (4) is moved adjacent to the hub [Figs. 4, 7 and 8; paraphgraph briding pages 6 and 7 and first full paragraph on page 7 as amended per Amendment dated August 5, 2003].

Claims 23 and 26, dependent respectively from independet claims 22 and 25, each define the latch member (20) to be integrated to the neck (12) [extending from the collar (4)] and is flexible relative to the collar [Figs. 1-4; paragraph bridging pages 6 and 7].

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether claims 1-6 and 22-27 are obvious over Hollister (US 5,139,489) in view of Thompson et al. (US 5,002,536) under 35 U.S.C. 103(a)?

2. Whether claims 22-27 are anticipated by Bachman et al. (US 5,733,265) under 35 U.S.C. 102(b)?

3. Whether claims 22-27 are anticipated by Gyure et al. (US 5,669,889) under 35 U.S.C. 102(b)?

ARGUMENT

1. 35 U.S.C. 103(a) rejection of claims 1-6 and 22-27 over Hollister (US 5,139,489) in view of Thompson et al. (US 5,002,536)

As discussed in the Summary of Claimed Subject Matter section above, the safety device of the instant invention comprises a collar that is slidably matable about a vial so that it is movable or positionable adjacent to one end of the needle hub of the vial. A neck or neck member extends from the collar, with a housing pivotably connected to the end of the neck or neck member away from the collar. A latch member that extends from the neck or the neck member in a direction toward the center of the collar would latch onto one end of the hub (claims 22 and 25) or coact with the shoulder of the hub (claim 1) when the collar is either positioned or moved adjacent to the hub (claim 1) or adjacent to one end of the hub (claims 22 and 25).

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motiviation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be reaonsable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all of the claimed limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclsoure. MPEP 2142.

Hollister (US 5,139,489) discloses a fluid tube holder (2), conventionally referred to as a Vacutainer holder, that has a main body (4 in Fig. 1 and 76 in Fig. 11) that the examiner has mistakenly referred to as a vial. As best shown in the exploded view of Fig. 1, extending from main body 4 of the fluid container holder 2 is a receptable end 6 (which the examiner considers a base in the Office Action). To the receptacle end there extends a rigid shoulder member 10 having an end 14 to which a housing 18 is connected by a living hinge 16. As clearly shown in Fig. 1, there is no needle hub provided at main body 4 of the fluid container holder 2. Rather, a double-ended needle assembly 20, which has a needle hub 24, is threaded to fluid container 2 by way of the opening 5, and more specifically by threading threaded portion 30 of needle hub 26 to the internal thread 42

formed at receptacle end 6 (column 4, lines 14-46). Hollister therefore fails to disclose a collar that can either slidably mate about a vial, or place about the vial and moved toward the hub of the vial.

Hollister does disclose an adapter (70 in the Fig. 4 and Fig. 11 embodiments). However, adapter 70 is interposed between the fluid container holder (76 in Figs. 4 and 11) and the double-ended needle assembly (Figs. 3 and 10; column 6, lines 23-27). Thus, even for the Figs. 4 and 11 embodiments, there is no collar disclosed in Hollister that is adapted to be slidably matable about (claim 1) or placed about (claims 22 and 25) a vial, as required by the being appealed claims of the instant invention.

Thompson was relied upon by the examiner as having disclosed "A collar (90, 45, 48), an extending flexible neck (area around 85, between end 34 and 41 of Fig. 2) and an integrated flexible latching member (44, 88) ..." [sentence bridging pages 2 and 3 of the Office Action].

In fact, Thompson discloses a hollow protective estastomeric sleeve (30 in Figs. 1 and 2 and 80 in Fig. 3) used to cap a needle 25 by friction fitting to a needle connector 20 to which a syringe is mated. In particular, the protective sleeve 30, in the Figs. 1 and 2 embodiment, comprises a hollow cone shaped member 32 having a large end opening 34 and a small end opening 36 that fits onto a hollow tube 40 (column 3, lines 37-47). The only "collar" disclosed in Thompson is a resilient collar 48 that extends around the proximal end of hollow tube 40 adjacent the reduced diameter end of hollow cone shape member 32 so as to form a resilient deformable outer shoulder at the end of hollow tube 40. This resilient deformable outer shoulder is used to grippingly engage the central portion of the tapered surface 21 of needle connector 20, when the protective sleeve is urged to and frictionally engages needle connector 20. To that end, lugs 44 are provided to tube 40 to engage with projections or ribs 22 at the needle connector 20 when sleeve 30 is frictionally fitted to needle connector 20 (column 3 lines 57-68). The so called collar and shoulder 48 of the Thompson protective sleeve are used to secure the protective sleeve to the needle connector 20, as lugs 44 engage projecting ribs 22 (column 4, lines 8-15 and also lines 23-26). The second embodiment of Thompson, as illustrated in Fig. 3, is a blood colletion system in whcih elastomeric sleeve 80 is used to cover needle 68 of the double-ended needle that fits to a Vacutainer holder 55. For the Fig. 3 embodiment, a deformable

estomeric collar 86 extends around the exterior of body portion 82, and inwardly extending lugs are formed inside bore 85 of the elastomeric sleeve 80. As disclosed in column 5, lines 13-26, "Collar 86 and lugs 88 lie in a common plane so that the connector sleeve 60 of the double-ended needle may be positioned in bore 85 of the elastomeric sleeve 80, as lugs 88 engage in the outer periphery of the splined portion 66 of the double-ended needle assembly to grippingly engage the splined portion 66 and the central portion 62 of the conenctor 60 of the double-ended needle. Note that collar 86 must be deformed or stretched for insertion of the connector 60 into bore 85 such that protective sleeve 80 will be firmly secured to end of cannula tube 55 to prevent removal thereof without application of substantial force to assure that the sleeve 80 will only be intentinally removed." Accordingly, the sleeve of the Fig. 3 embodiment, as well as the earlier discussed embodiment, of Thompson is removalbe from the needle after the needle has been covered by the elastomeric sleeve. In sum, according to the teachings of Thompson, the "collar" as disclosed in Thompson refers to the portion of the sleeve that grips onto the needle hub (needle connector 20 or cannula connector 60) when the sleeve is press fitted to the needle connector.

1A. Independent claims 1, 22, 25

There is no disclosure in Thompson and/or Hollister of a flexible neck that extends from a collar and a latch member that extends from the neck member that coacts with the shoulder of the hub and the distal end of the collar coacting with the base of the hub to prevent the collar from being removed from the vial once the collar has been mated about the vial and the distal end of the collar is positioned adjacent to the hub, as set forth in claim 1.

For that matter, Thompson and/or Hollister do not disclose any latch member that extends from the neck that would latch onto another end of the hub when the collar is placed about the vial and moved toward the hub of the vial until it is adjacent to one end of the hub, as recited in claim 22.

Further, neither Thompson nor Hollister discloses any latch member that extends from the neck that continuously biases against the body of the vial when the collar is placed about the vial and moved toward one end of the hub of the vial. In other words,

there is nothing is the prior art that suggests the latch member biasing against the hub as the collar is moved toward one end of the hub, with the latch member finally latching onto another end of the hub when the collar is moved adjacent to the one end of the hub, as recited in claim 25.

Finally, Thompson discloses that its needle protection sleeve may be removed from the needle hub, which is not the case with respect to the claimed collar, which once positioned adjacent to the hub, is not removable therefrom.

In sum, there is no disclosure in either Hollister or Thompson of the latch member as required by the being appealed independent claims 1, 22 and 25.

There is moreover no suggestion or motiviation provided by either Hollister or Thompson that those references be combined per asserted by the examiner. To wit, Hollister discloses a Vacutainer to which there is a needle protective housing is either integrally formed to the Vacutainer holder or is an adapter that mounts to the receptacle end of the Vacutainer holder, per shown in the embodiments of Figs. 4, 8, 11 and 12. There simply is no motivation on the part of Hollister to have his housing fitted to a collar, and then slidably move the collar about the Vacutainer body. This is clear since there would not be any place on the Vacutainer body for the collar to be latched onto. On the other hand, the Thompson tubular hollow needle protection sleeve is specially designed to be elastomeric so that it may expand and grip onto the needle hub. There is nothing in Thompson that suggests that his "collar" is meant to be fitted about a vial and movable therealong or repositioned along the vial. This is clear insofar as the so-called collar disclosed in Thompson is flexible and is meant to grip the needle hub. Further, given that Thompson and Hollister each disclose their own needle protective device, and furthermore that the Thompson elastomeric needle sleeve needs to be press fit onto a needle hub, it would be hard-pressed for one skilled in the art to combine the teachings of Hollister and Thompson per asserted by the examiner. So too, it is highly unlikely, if not impossible, for the so-called elastomeric "collar" disclosed in Thompson to be combined with the rigid shoulder member 10 of the Hollister device.

Appellant therefore respectfully submits that there is no suggestion or motivation in either Hollister or Thompson to enable one of ordinary skill in the art to modify those

references as asserted by the examiner to reject being appealed independent claims 1, 22 and 25.

It is well established that, in rejecting an application, the examiner cannot take into consideration only particular portions of a reference while ignoring other portions of the same reference. The rejection by the examiner in the instant case is a classic example of such prohibited pick and choose technique in which the examiner, having in front of him the teachings of the at issue application, picks and chooses only portions of prior art references while ignoring the actual teachings of those references. For how else could the elastomeric tube of Thompson be considered an upright (1st full sentence on page 3 of Office Action) to which the distal end the housing 18 of Hollister is deemed to be attachable? It is difficult to imagine one skilled in the art would have considered the elastomeric sleeve of Thompson to be a neck member to which a housing may be attached. To elaborate, given that the purpose of the elastomeric sleeve of Thompson is to cover the needle, why would a person skilled in the art reconfigure the elastomeric sleeve of Thompson as an upright in order to attach to it the housing of Hollister when in fact the elastomeric sleeve of Thompson already is a needle protective housing? If anything, the assumptions made by the examiner to reject claims 1, 22 and 25 smack of a classic case of hindsight, which, absent any motivation or suggestion in the references, is prohibited and not sustainable.

Appellant therefore respectfully submits that each of independent claims 1, 22 and 25 is not obvious over the combination of Hollister and Thompson.

1B. Dependent claims 2, 3, 4, 23, 26

Appellant submits that Hollister and Thompson, either singly or in combination, disclose a flexible neck member, as recited in claims 2, 3, 4, 23 and 26. The so-called "neck member" asserted by the examiner as being disclosed in Thompson in actuality is a part of the tubular hollow tube of the elastomeric sleeve.

Appellant respectfully submits that none of the limitations as noted in the Summary of Invention Section above that define the configuration of the latch member as set forth

in claim 3 is disclosed by the combination of Hollister and Thompson. For example, Thompson and Hollister fail to disclose or suggest the latch member being integrated to a location along the neck member so as to effect a space between the latch member and the collar along the neck member whereinto the hub matingly fits after the collar is moved adjacent to the hub and the latch member is moved into position to latch onto the shoulder of the hub.

The same is true with respect to claim 4 which requires "said needle and said housing interact to prevent said neck member from flexing away from said hub and said latch member from being disengaged from said shoulder of said hub". The combination of Hollister and Thompson fails to disclosure such.

Appellant further respectfully submits that the Hollister/Thompson combination fails to disclose or suggest the flexible upright neck member of claim 6 and the particular configuration of the latch member as recited in claim 6.

Appellant furthermore respectfully submits that the Hollister/Thompson combination fails to disclose or suggest the limitation of the latch member being integrated to the neck and flexible relative to the collar as recited in claims 23 and 26.

In view of the above, appellant respectfully submits that each of the independent claims 1, 22 and 25 and the dependant claims 2, 3, 4, 23, 26 discussed above is non-obvious over Hollister in view of Thompson.

2. Anticipation rejection of claims 22-27 under 35 U.S.C. 102(b) by Bachman et al. (US 5,733,265)

"For a prior art reference to anticipate in terms of 35 U.S.C. 102, every element of the claimed invention must be identically shown in a single reference." *In re Bond*, 910 F.2d 831, 832 (Fed. Cir. 1990). Anticipation under 35 U.S.C. 102(e) requires that "`[e]ach and every element as set forth in the claim is found either expressly or inherently described, in a single prior art reference'". *In re Robertson*, 169 F.3d. 743, 746 (Fed. Cir. 1999).

Moreover, to anticipate a claim, MPEP 2131 states: "A claim is anticipated only if each and every element of the claim is found, either expressly or inherently described, in a single prior art reference.", and "The identical invention must be shown in as complete detail and is contained in the .... claim."

In rejecting claims 22-27 under 35 U.S.C. 102(b) as being anticipated by Bachman, the examiner relied upon Bachman to show "a collar slidably matable about said [collar]", "a neck member extending from the collar 48", "a housing 32 pivotally connected to the end of the neck member away from the collar", "a latch member 70 extending from the neck member in a direction towards the center of the collar, the latch member coacting with the hub to prevent the collar from being removed from the vial once the collar has been mated about the vial and moved to be substantially the hub". Page 4 of the Office Action dated March 24, 2006.

As was pointed out above in the Summary of Invention section, each of claims 22 and 25 recites a collar, a neck extending from the collar, a housing pivotably connected to the end of the neck away from the collar, and a latch member extending from the neck in a direction towards the center of the collar. Moreover, claim 22 specifically recites "wherein when said collar is placed about a vial and moved toward a hub of said vial until adjacent to one end of said hub, said latch member is latched onto another end of said hub", and claim 25 recites "said latch member continuously biases against body of a vial when said collar is placed about said vial and moved toward one end of a hub of said vial, said latch member further biases against said hub as said collar is moved further toward said one end of said hub, said latch member latching onto another end of said hub when said collar is moved adjacent to said one end of said hub".

Bachman does not disclose anything close to the safety device set forth in claims 22 or 25. In particular, Bachman does not disclose any collar "placed about a vial and moved toward one end of a hub of a vial". Nor does Bachman disclose any "neck" connecting the collar to a housing, or a "latch member" that extends from the neck.

At best, Bachman discloses a mount 48 that includes an opening 49 that is sized and shaped to receive at least a portion 53 of a needle hub 20 (column 4, lines 62-64; Fig. 1). As shown in Figs. 1 and 3-4, needle hub 20 clearly is not a vial, as it is arranged to be

releasably mounted to a syringe via its proximal end 22. It is well understood in the medical art that a syringe is not a vial.

In fact, as best shown by the exploded perspective view of Fig. 1, the needle assembly 10 disclosed by Bachman includes a needle hub 20 to which mount 48 is to be mounted at its distal portion 53. A sheath 32 is connected to mount 48 by a hinge 46 (Figs. 2 and 3). Further, prior to use and for transport, a cover 50 is slid over sheath 32 (Fig. 2). A more detailed overall discussion of the various components of the Bachman needle assembly is provided in column 4, line 45 to column 5, line 23.

The examiner asserts that Bachman discloses "a latch member 70 extending from the neck member in a direction towards the center of the collar, the latch member coacting with the hub to prevent the collar from being removed from the vial once the collar has been mated about the vial and moved to be substantially adjacent the hub." (Page 2 of the May 24, 2006 Office Action).

In fact, Bachman discloses, or suggests, none of the quoted limitations.

The alleged "latch member 70" in actuality is a proximal raised retention area on the exterior surface 70 of each sidewall 38 of the elongate shield 32 of the needle assembly 10 disclosed by Bachman (column 5, lines 38-43). In fact, retention areas 70 at elongate shield 32 are used to coact with two rails 69 on the inside surface 51 of cover 50 (see rails 69 in Figs. 9 and 10), so as to retain cover 50 onto shield 32 when the needle assembly is being shipped and before use (column 5, lines 43-49). The needle assembly 10 is shown in its initial closed position in Figs. 2 and 6. Thus, raised retention areas 70 of elongate shield 32 in actuality have nothing to do with mount 48 for the Bachman device. Putting it simply, component 70 shown in Fig. 1 of Bachman does not coact with anything on mount 48, or needle hub 20, for preventing mount 48 from being removed from needle hub 28. Rather, for the Bachman device, to maintain mount 48 to needle hub 20, an annular groove 78 is formed at the interior surface 79 of mount 48. This annular groove engages a raised projection 21 at needle hub 20, so that mount 48 is retained to needle hub 20 and is rotatable at less than one rotation about needle hub 20 (Fig. 1; column 6, lines 30-40).

Thus, the actual usage of retention areas 70 at elongate shield 32 is to retain cover 50 in shield 32 before the needle assembly is to be used. Given the respective configurations of raised retention areas 70 at elongate shield 32 and rails 69 at the interior surface of cover 50, when the needle assembly is to be used, cover 50 is moved axially in the distal direction. As it is thus moved, a protuberance 73 engages the proximal edge 74 (Figs. 8, 9 and 10) to cause shield 32 to pivot about hinge 46 and move to the open position as shown in Fig. 3 (column 5, lines 38-49). Once cover 50 is removed, elongate shield 32 is pivoted away from needle 12 with a cantilever spring 66 that provides resistance force against elongate shield 32 to thereby prevent the latter from being closed over needle 12, unless a sufficient force is used (column 5, lines 49-55). Needle 12 may then be used.

In sum, Bachman fails to disclose: (1) a vial, (2) a collar that slides over the vial, (3) a latch member extending from the neck member in a direction towards the center of the collar, and (4) when the collar placed about the vial is moved toward a hub [or one end of the hub] of the vial, the latch member would latch onto another end of the hub when the collar is moved adjacent to the one end of the hub. Nothing in Bachman therefore remotely discloses or suggests the claimed invention.

In view of the above, appellant respectfully submits that the anticipation rejection of being appealed claims 22-27 by Bachman is without merit and not sustainable.

3. Anticipation rejection of claims 22-27 under 35 U.S.C. 102(b) over Gyure et al. (US 5,669,889)

In the rejection, the examiner asserts that Gyure teaches "... a neck member (44) extending from the collar (41); and a latch member (69) extending from the neck member in a direction towards the center of the collar, the latch member coacting with the hub to prevent the collar from being removed from the vial once the collar has been mated about the vial and moved to be substantially adjacent the hub." (Page 4 of the Office Action dated May 24, 2006).

Appellant respectfully submits that the alleged "latch member 69" is not a latch member at all. Rather, component 69 of the Gyure device is a finger pad that is used to close the needle shield 45 over a needle 21. In particular, with reference to Figs. 6 and 7 and the disclosure in column 6, lines 7-15, it is clear that once the needle shield and collar assembly as shown in Fig. 3 is assembled to the hub of the needle and the syringe 70 (Fig. 2), to move needle shield 45 from its open position as shown in Fig. 6 to the closed position as shown in Fig. 7, a user would press on the back wall 53 of needle shield 45. According to Gyure, finger pad 69 is provided to facilitate the movement of needle shield from the open to the closed position in a single-handed operation. Thus, element 69 of the Gyure device is not a latch member, or in any way is used for latching the collar to the hub of a vial.

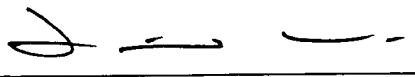
Indeed, Gyure does not disclose any latch member extending from the neck of a collar in a direction toward the center of the collar.

In view of the foregoing, appellant respectfully submits that the anticipation rejection of being appealed claims 22-27 in view of Gyure is without merit and not sustainable.

4. Conclusion

in view of the above, appellant respectfully submits that all three grounds of rejection by the examiner are not sustainable and should be reversed.

Respectfully submitted,



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Date: Sept 13, 2006

CLAIMS APPENDIX A

1. Safety device usable with a vial, said vial having mounted to one of its ends a hub from which a needle extends, said hub having a shoulder and a base, said safety device comprising:

a collar slidably matable about said vial, said collar having a distal end;

a neck member extending from the distal end of said collar;

a housing pivotably connected to end of said neck member away from said collar; and

a latch member extending from said neck member in a direction towards center of said collar, said latch member coacting with the shoulder of said hub and the distal end of said collar coacting with the base of said hub to prevent said collar from being removed from said vial once said collar has been mated about said vial and the distal end of said collar is positioned adjacent said hub.

2. Safety device of claim 1, wherein said latch member is integrated to said neck member; and

wherein said neck member is flexible with respect to said collar so that said latch member is guided along the side of said hub as said collar is moved towards said hub, said latch member latching onto a shoulder of said hub when said collar is moved adjacent to said hub.

3. Safety device of claim 1, wherein said latch member is integrated to a location along said neck member so as to effect a space between said latch member and said collar along said neck member whereinto said hub matingly fits after said collar is moved adjacent to said hub and said latch member is moved into position to latch onto a shoulder of said hub.

4. Safety device of claim 1, wherein said neck member is flexible with respect to said collar so that once said collar is moved to a given position relative to said hub, said neck member flexes to a position to enable said latch member to latch onto a shoulder of said hub; and

wherein said housing comprises a slot wherethrough said needle passes when said housing is pivoted to a position in substantial alignment with the longitudinal axis of said vial, said housing further including at least one locking means for fixedly maintaining said needle relative to said housing once said housing is pivoted to said alignment position;

wherein once fixed relative to each other, said needle and said housing interact to prevent said neck member from flexing away from said hub and said latch member from being disengaged from said shoulder of said hub.

5. Safety device of claim 4, wherein said locking means comprises a hook integrated to interior of said housing for holding said needle fixed relative to said housing once said housing is pivoted to said alignment position and said needle biases and then is held by said hook.

6. Safety device of claim 1, wherein said neck member comprises a flexible upright extending from said collar, and wherein said latch member comprises a lip extending at its tip, said lip latching onto a shoulder of said hub when said collar is moved adjacent to said hub.

22. Safety device, comprising:

a collar;

a neck extending from said collar;

a housing pivotably connected to the end of said neck away from said collar; and

a latch member extending from said neck in a direction towards the center of said collar;

wherein when said collar is placed about a vial and moved toward a hub of said vial until adjacent to one end of said hub, said latch member is latched onto another end of said hub.

23. Safety device of claim 22, wherein said latch member is integrated to said neck and flexible relative to said collar.

24. Safety device of claim 22,wherein said housing comprises at least one integral hook for lockingly gripping a needle extending from said hub when said housing is pivoted to a position in alignment along longitudinal axis of said vial.

25. Safety device, comprising: a collar, a flexible neck extending from said collar, a housing pivotably connected to the end of said neck away from said collar, and a latch member extending from said neck in a direction towards the center of said collar, said latch member continuously biases against body of a vial when said collar is placed about said vial and moved toward one end of a hub of said vial, said latch member further biases against said hub as said collar is moved further toward said one end of said hub, said latch member latching onto another end of said hub when said collar is moved adjacent to said one end of said hub.

26. Safety device of claim 25, wherein said latch member is integrated to said neck and flexible relative to said collar.

27. Safety device of claim 25, wherein said housing comprises at least one integral hook for lockingly gripping a needle extending from said hub when said housing is pivoted to a position in alignment along longitudinal axis of said vial.

CLAIMS APPENDIX B

7. (Withdrawn) Safety device usable with a vial, said vial having mounted to one of its ends a hub from which a needle extends, said safety device comprising:

a collar slidably matable about said vial;

a support member extending from said collar;

a housing pivotably connected to the end of said support member away from said collar; and

a latch member extending from said collar in planar relationship with said support member, said latch member being flexible relative to said support member so as to coact with said hub to prevent said collar from being removed from said vial once said collar has been mated about said vial and moved substantially adjacent to said hub.

8. (Withdrawn) Safety device of claim 7, wherein said support member comprises a frame extending from said collar and wherein said latch member extends from said collar to fit within the confines of said support frame, said latch member being guided along said hub as said collar is moved towards said hub and latches onto a shoulder of said hub when said collar is moved adjacent to said hub.

9. (Withdrawn) Safety device of claim 7, wherein said support member is a rigid member and said latch member comprises a flexible upright extending from said collar and a lip extending at its tip, said lip latching onto a shoulder of said hub when said collar is moved adjacent to said hub.

10. (Withdrawn) Safety device of claim 7, wherein said latch member is flexible with respect to said collar so that once said collar is moved to a given position relative to said hub, said latch member latches onto a shoulder of said hub; and

wherein said housing comprises a slot wherethrough said needle passes when said housing is pivoted to a position in substantial alignment with the longitudinal axis of said vial, said housing further including at least one locking means for fixedly maintaining said needle relative to said housing once said housing is pivoted to said alignment position;

wherein once fixed relative to each other, said needle and said housing interact to prevent said latch member from flexing away and disengaged from said hub.

11. (Withdrawn) Safety device of claim 10, wherein said locking means comprises a hook integrated to the interior of said housing for holding said needle fixed relative to said housing once said housing is pivoted to said alignment position and said needle biases and then is held by said hook.

12. (Withdrawn) Safety device of claim 7, wherein said vial further comprises a gasket slidable along the length of said vial, said vial with said collar positioned adjacent said hub

being placed into a cavity of a holder, said gasket being coupled to a plunger slidable along the length of said holder;

wherein fluid stored in said vial is ejected out of said vial through said needle when said plunger is pushed towards said hub.

13. (Withdrawn) In combination,

a collar slidably matable about a vial having a hub from which a needle extends;

a neck member extending from said collar;

a housing pivotably connected to the end of said neck member away from said collar,

a latch member positioned relative to said neck member coacting with said hub to prevent said collar from being removed from said vial once said collar has been mated about said vial and moved to be substantially adjacent said hub; and

a holder having a cavity into which said vial having said collar mounted thereabout is fitted.

14. (Withdrawn) Combination of claim 13, wherein said latch member integrally extends from said neck member in a direction towards the center of said collar, said neck member being flexible with respect to said collar so that said latch member is guided along the side of said hub as said collar is moved towards said hub, said latch member latching onto a shoulder of said hub when said collar is moved adjacent said hub.

15. (Withdrawn) Combination of claim 13, wherein said latch member is integrated to a location along said neck member so as to effect a space between said latch member and said collar along said neck member whereinto said hub matingly fits after said collar is moved adjacent said hub and said latch member is moved into position to latch onto a shoulder of said hub.

16. (Withdrawn) Combination of claim 13, wherein said neck member comprises a rigid support frame extending from said collar; and

wherein said latch member extends from said collar to fit within the confines of said support frame, said latch member being guided along said hub as said collar is moved towards said hub and latches onto a shoulder of said hub when said collar is moved adjacent to said hub.

17. (Withdrawn) Combination of claim 13, wherein said neck member is flexible with respect to said collar so that once said collar is moved to a given position relative to said hub, said neck member flexes to a position to enable said latch member to latch onto a shoulder of said hub; and

wherein said housing comprises a slot wherethrough said needle passes when said housing is pivoted to a position in substantial alignment with the longitudinal axis of said

vial, said housing further including at least one locking means for fixedly maintaining said needle relative to said housing once said housing is pivoted to said alignment position;

wherein once fixed relative to each other, said needle and said housing interact to prevent said neck member from flexing away from said hub and said latch member from being disengaged from said shoulder of said hub.

18. (Withdrawn) Combination of claim 13, further comprising:

a gasket slidable along the length of said vial;

a plunger slidable along the length of said holder;

wherein said gasket is coupled to said plunger when said vial with said collar positioned adjacent said hub is fitted into said cavity of said holder so as to eject fluid stored in said vial through said needle when said plunger is pushed towards said hub.

19. (Withdrawn) Combination of claim 13, wherein said holder further comprises a turnable base member that, when rotated in one direction, would come into contact with the end of said vial away from said hub to thereby apply a biasing force against said vial to forcibly maintain said vial inside said cavity of said holder and said collar secured to said vial.

20. (Withdrawn) A method of attaching a needle protection housing to a vial, a hub formed at one end of said vial and a needle extending from said hub, comprising the steps of:

attaching said housing to a collar via a neck member;

extending from said neck member a latch member in a direction towards the center of said collar;

fitting said collar about said vial; and

moving said collar relative to said hub until said latch member latches onto a given portion of said hub to prevent said collar from moving away from said hub.

21. (Withdrawn) Method of claim 20, further comprising the steps of:

placing said vial fitted with said collar into a holder;

actuating a mechanism integral of said holder to apply a biasing force to said vial to securely retain said vial within said holder.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.

CITATIONS